SEP - 4 2001

K012799

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

1. SUBMITTER INFORMATION

a. Company Name:	SenoRx Inc.
b. Company Address:	11 Columbia, Suite A Aliso Viejo CA 92656
c. Telephone: Facsimile:	(949) 362-4800 (949) 362-3519
d. Contact Person:	Amy Boucly Director, Regulatory Affairs And Quality Assurance
e. Date Summary Prepared:	August 30, 2001

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	ES-2000 Generator System and Shape Select Electrosurgical Scalpel
b. Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories 878.4400

3. IDENTIFICATION OF PREDICATE DEVICES

Force FX	Valleylab, Incorporated, K944602
Surgitron IEC II	Ellman International, Inc., K001253, K001407
Bovie Hand Control	Sybron Corporation, K790187

4. DESCRIPTION OF THE DEVICE

The ES-2000 Electrosurgical Generator and Shape Select Electrosurgical Scalpel are designed to cut and coagulate soft tissue. The ES-2000 uses radio frequency (RF) energy to perform both cutting and coagulation, using SenoRx compatible disposable handpieces.

5. STATEMENT OF INTENDED USE

The SenoRx ES-2000 Electrosurgical Generator and Shape Select Electrosurgical Scalpel and their accessories are intended for general procedures where electrosurgical cutting or coagulation of soft tissues is required

6. COMPARISON WITH PREDICATE DEVICES

The intended use, design, construction, material and nominal specifications are comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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SenoRx, Inc.
c/o Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, Massachusetts 01779

Re: K012799
Trade/Device Name: ES-2000 Generator System and Shape Select™ Scalpel
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: July 31, 2001
Received: August 21, 2001

Dear Mr. Sherratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Walker, M.D.
for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2 FDA Indications for Use Page

510(k) number (if known): K012799

Device Name: ES-2000 Generator System and Shape Select™ Scalpel

Indications for Use:

The SenoRx ES-2000 electrosurgical generator and accessories are intended for general surgical procedures where electrosurgical cutting or coagulation of soft tissues is required. It is not intended for use on the skin or where electrosurgery is contraindicated.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012799